K113262

JUL 3 2012

510(k) SUMMARY

510(k) Owner:	Alfa Wassermann Diagnostic Technologies, LLC 4 Henderson Drive West Caldwell, NJ 07006 Contact: Hyman Katz, Ph.D. Phone: 973-852-0158 Fax: 973-852-0237	
Date Summary Prepared:	November 3, 2011	
Device:	Trade Name: System	ACE Axcel Clinical Chemistry
	Classification:	Class 1
	Common/Classification Name:	Analyzer, Chemistry (Photometric, Discrete), For Clinical Use (21 C. F.R. § 862.2610) Product Code JJE
	Trade Name:	ACE Cholesterol Reagent
	Classification:	Class 1
	Common/Classification Name:	Enzymatic Esterase-Oxidase, Cholesterol (21 C. F.R. § 862.1175) Product Code CHH
	Trade Name:	ACE HDL-C Reagent
	Classification:	Class 1
	Common/Classification Name:	LDL & VLDL Precipitation, Cholesterol Via Esterase-Oxidase, HDL (21 C. F.R. § 862.1475) Product Code LBS
	Trade Name:	ACE LDL-C Reagent
	Classification:	Class 1
	Common/Classification Name:	System, Test, Low Density, Lipoprotein (21 C. F.R. § 862.1475)

		Product Code MRR
	Trade Name:	ACE Triglycerides Reagent
	Classification:	Class 1
	Common/Classification Name:	Lipase Hydrolysis/Glycerol Kinase Enzyme, Triglycerides (21 C. F.R. § 862.1705) Product Code CDT
Predicate Devices:	Manufacturer for analyzer/reagent system predicates: Alfa Wassermann ACE plus ISE/Clinical Chemistry System (K931786) ACE Cholesterol Reagent (K931786) ACE HDL-C Reagent (K971526) ACE LDL-C Reagent (K991733) ACE Triglycerides Reagent (K931786)	
Device Descriptions:	The ACE Axcel Clinical Chemistry System consists of two major components, the chemistry instrument and an integrated Panel PC. The instrument accepts the physical patient samples, performs the appropriate optical or potentiometric measurements on those samples and communicates that data to an integral Panel PC. The Panel PC uses keyboard or touch screen input to manually enter a variety of data, control and accept data from the instrument, manage and maintain system information and generate reports relative to patient status and instrument performance. The Panel PC also allows remote download of patient requisitions and upload of patient results via a standard interface. In the ACE Cholesterol Reagent assay, cholesterol esters in serum are completely hydrolyzed by cholesterol esterase to free cholesterol and free fatty acids. The cholesterol liberated by the esterase, plus any endogenous free cholesterol, are both oxidized by cholesterol oxidase to yield hydrogen peroxide. The hydrogen peroxide then acts to oxidatively couple p-hydroxybenzoic acid and 4-aminoantipyrine in a reaction catalyzed by peroxidase, producing a red colored quinoneimine complex which absorbs strongly at 505 nm. The amount of chromogen formed, determined by measuring the increase in absorbance, bichromatically at 505 nm/647 nm, is directly proportional to the cholesterol concentration in the sample. The HDL-C Assay utilizes two reagents, the second containing a unique detergent. This detergent solubilizes only the HDL lipoprotein particles, thus releasing HDL cholesterol to react with the cholesterol esterase and cholesterol oxidase, in the presence of a chromogen to produce color. The detergent also inhibits the reaction of the cholesterol	

	enzymes with LDL, VLDL and chylomicron lipoproteins by adsorbing to their surfaces. The amount of chromogen formed, determined by measuring the increase in absorbance bichromatically at 592/692 nm, is directly proportional to the HDL cholesterol concentration in the sample. In the ACE LDL-C Reagent assay, detergent 1 solubilizes non-LDL lipoprotein particles (HDL, VLDL and chylomicrons) and releases cholesterol. The cholesterol is consumed by cholesterol esterase and cholesterol oxidase in a non-color forming reaction. In a second reaction, detergent 2 solublizes the remaining LDL particles and forms peroxide, via the enzymes cholesterol esterase and cholesterol oxidase. The peroxide, in the presence of peroxidase and two peroxidase substrates, 4-aminoantipyrine and DSBmT, results in a purple-red color. The amount of color formed, determined by measuring the increase in absorbance bichromatically at 544/692 nm, is directly proportional to the LDL cholesterol concentration in the sample. In the ACE Triglycerides Reagent Assay, triglycerides in serum are hydrolyzed by lipase to form glycerol and free fatty acids. In the presence of adenosine triphosphate (ATP) and glycerol kinase, the glycerol is converted to glycerol-1-phosphate and the ATP to adenosine diphosphate. Glycerol-1-phosphate is oxidized by glycerol phosphate oxidase to yield hydrogen peroxide. The hydrogen peroxide then acts to oxidatively couple p-chlorophenol and 4-aminoantipyrine in a reaction catalyzed by peroxidase, producing a red colored quinoneimine complex which absorbs strongly at 505 nm. The amount of chromogen formed, determined by measuring the increase in absorbance bichromatically at 505 nm/692 nm, is directly proportional to the triglycerides concentration in the sample.
Intended Use:	Indications for Use: The ACE Axcel Clinical Chemistry System is an automated, discrete, bench-top, random access analyzer that is intended for *in vitro* diagnostic use in the quantitative determination of constituents in blood and other fluids. The ACE Cholesterol Reagent is intended for the quantitative determination of cholesterol concentration in serum using the ACE Axcel Clinical Chemistry System. Cholesterol measurements are used in the diagnosis and treatment of disorders involving excess cholesterol in the blood and lipid and lipoprotein metabolism disorders. This test is intended for use in clinical laboratories or physician office laboratories. For in vitro diagnostic use only.

	The ACE HDL-C Reagent is intended for the quantitative determination of high density lipoprotein cholesterol (HDL-C) concentration in serum using the ACE Axcel Clinical Chemistry System. Lipoprotein measurements are used in the diagnosis and treatment of lipid disorders (such as diabetes mellitus), atherosclerosis, and various liver and renal diseases. This test is intended for use in clinical laboratories or physician office laboratories. For in vitro diagnostic use only. The ACE LDL-C Reagent is intended for the quantitative determination of low density lipoprotein cholesterol (LDL-C) concentration in serum using the ACE Axcel Clinical Chemistry System. Lipoprotein measurements are used in the diagnosis and treatment of lipid disorders (such as diabetes mellitus), atherosclerosis, and various liver and renal diseases. This test is intended for use in clinical laboratories or physician office laboratories. For in vitro diagnostic use only. The ACE Triglycerides Reagent is intended for the quantitative determination of triglyceride concentration in serum using the ACE Axcel Clinical Chemistry System. Triglyceride measurements are used in the diagnosis and treatment of patients with diabetes mellitus, nephrosis, liver obstruction, other diseases involving lipid metabolism or various endocrine disorders. This test is intended for use in clinical laboratories or physician office laboratories. For in vitro diagnostic use only.
Technological Characteristics:	The following is a description of the major features of the ACE Axcel Clinical Chemistry System: • System throughput is approximately 160 test results per hour for routine, single reagent chemistries. System throughput will be higher when the test workload includes ISE's. • The instrument has a capacity of 40 reagent containers on board. A reagent cooling system maintains the reagents at 12°C during instrument operation. • Reagent containers are identified by computer coded labels to simplify system operation. All reagents in the system must include an identification label on the container. • Sample and reagent sensing notify the operator of a depleted condition during operation. • The system performs analysis at a reaction temperature of 37°C. • An electrolyte subsystem capable of measuring sodium, potassium and chloride concentrations is included. • Primary draw tubes may be introduced one at a time into the system for closed tube sampling. Positive tube identification can be achieved with an optional barcode scanner. An aliquot volume sufficient for all tests ordered is transferred and stored and the

	closed tube is returned to the user. • Sample cups are introduced to the system one at a time or by sample ring segment. • Disposable cuvettes are loaded in bulk and then automatically injected as needed by a cuvette hopper system. The ACE Axcel clinical chemistry optical system is capable of monitoring a maximum of 48 cuvettes at one time. • The absorbance optical system is capable of absorbance measurements in a linear range of 0.0 to 2.0 absorbance units (at 0.67 cm pathlength). Sixteen wavelengths are measured simultaneously using a photodiode array. The ACE Cholesterol Reagent is composed of a single reagent bottle. The reagent contains 4-aminoantipyrine, p-hydroxybenzoic acid, cholesterol oxidase, cholesterol esterase and peroxidase. The ACE HDL-C Reagent is composed of two reagent bottles (Buffer and Color Reagent). The reagents contain Good's buffer, cholesterol oxidase, peroxidase, N,N-bis(4-sulphobutyl)-m-toluidine-disodium salt, ascorbic oxidase, cholesterol esterase 4-aminoantipyrine and a detergent. The ACE LDL-C Reagent is composed of two reagent bottles (Buffer and Color Reagent). The reagents contain MES Buffer (pH 6.3), detergent 1, cholesterol esterase, cholesterol oxidase, peroxidase, 4-aminoantipyrine, ascorbic acid oxidase, detergent 2 and N,N-bis(4-sulphobutyl)-m-toluidine-disodium salt. The ACE Triglycerides Reagent is composed of a single reagent bottle. The reagent contains aminoantipyrine, adenosine 5'-triphosphate, p-chlorophenol, glycerol phosphate oxidase, lipase, peroxidase and glycerol kinase.
Performance Data:	Performance data for the Alfa Wassermann ACE Reagents run on the Alfa Wassermann ACE Axcel Clinical Chemistry System included precision, accuracy, and detection limit data. <u>ACE Cholesterol Reagent</u> <u>Precision</u>: In testing conducted at four cholesterol levels for 22 days, the within-run CV ranged from 1.3 to 2.0%, and total CV ranged from 1.6 to 2.2%. In precision studies at three separate Physician Office Laboratory (POL) sites over 5 days, the within-run CV ranged from 0.7 to 1.5% and total CV ranged from 1.0 to 1.7%. <u>Accuracy</u>: In the correlation study, 110 samples with cholesterol values ranging from 7 to 527 mg/dL were assayed on the Alfa Wassermann

	ACE Axcel Clinical Chemistry System (y) and the Alfa Wassermann ACE Clinical Chemistry System (x). Least squares regression analysis yielded a correlation coefficient of 0.9977, a standard error estimate of 5.0, a confidence interval slope of 0.999 to 1.026, and a confidence interval intercept of -6.2 to -0.5. In patient correlation studies at three separate POL sites, using the Alfa Wassermann ACE Axcel Clinical Chemistry System (y) and the Alfa Wassermann ACE Clinical Chemistry System (x), least-squares regression analysis yielded correlation coefficients of 0.9945 to 0.9995, standard error estimates of 3.0 to 8.4, confidence interval slopes of 0.964 to 1.034, and a confidence interval intercepts of -7.3 to 6.7. Detection limit: The detection limit was 3.6 mg/dL. ACE HDL-C Reagent Precision: In testing conducted at four HDL-C levels for 22 days, the within-run CV ranged from 1.4 to 2.7%, and total CV ranged from 3.2 to 4.8%. In precision studies at three separate Physician Office Laboratory (POL) sites over 5 days, the within-run CV ranged from 0.7 to 2.6% and total CV ranged from 1.1 to 3.5%. Accuracy: In the correlation study, 109 samples with HDL-C values ranging from 4 to 122 mg/dL were assayed on the Alfa Wassermann ACE Axcel Clinical Chemistry System (y) and the Alfa Wassermann ACE Clinical Chemistry System (x). Least squares regression analysis yielded a correlation coefficient of 0.9959, a standard error estimate of 1.7, a confidence interval slope of 0.956 to 0.990, and a confidence interval intercept of -0.5 to 1.4. In patient correlation studies at three separate POL sites, using the Alfa Wassermann ACE Axcel Clinical Chemistry System (y) and the Alfa Wassermann ACE Clinical Chemistry System (x), least-squares regression analysis yielded correlation coefficients of 0.9898 to 0.9970, standard error estimates of 1.7 to 2.4, confidence interval slopes of 0.936 to 1.061, and a confidence interval intercepts of -3.8 to 2.0. Detection limit: The detection limit was 1.5 mg/dL. ACE LDL-C Reagent Precision: In testing conducted at four LDL-C levels for 22 days, the within-run CV ranged from 2.5 to 4.6%, and total CV ranged from 3.2 to 4.9%. In precision studies at three separate Physician Office Laboratory (POL) sites over 5 days, the within-run CV ranged from 1.7

	to 4.4% and total CV ranged from 2.4 to 5.9%. Accuracy: In the correlation study, 108 samples with LDL-C values ranging from 10 to 422 mg/dL were assayed on the Alfa Wassermann ACE Axcel Clinical Chemistry System (y) and the Alfa Wassermann ACE Clinical Chemistry System (x). Least squares regression analysis yielded a correlation coefficient of 0.9973, a standard error estimate of 4.7, a confidence interval slope of 0.968 to 0.996, and a confidence interval intercept of -3.1 to 1.0. In patient correlation studies at three separate POL sites, using the Alfa Wassermann ACE Axcel Clinical Chemistry System (y) and the Alfa Wassermann ACE Clinical Chemistry System (x), least-squares regression analysis yielded correlation coefficients of 0.9940 to 0. 9974, standard error estimates of 5.9 to 9.0, confidence interval slopes of 0.991 to 1.071, and a confidence interval intercepts of -8.4 to 4.0. Detection limit: The detection limit was 4.0 mg/dL. ACE Triglycerides Reagent Precision: In testing conducted at four triglycerides levels for 22 days, the within-run CV ranged from 1.2 to 2.9%, and total CV ranged from 1.8 to 3.2%. In precision studies at three separate Physician Office Laboratory (POL) sites over 5 days, the within-run CV ranged from 0.5 to 2.3% and total CV ranged from 0.6 to 4.1%. Accuracy: In the correlation study, 111 samples with triglycerides values ranging from 18 to 996 mg/dL were assayed on the Alfa Wassermann ACE Axcel Clinical Chemistry System (y) and the Alfa Wassermann ACE Clinical Chemistry System (x). Least squares regression analysis yielded a correlation coefficient of 0.9995, a standard error estimate of 6.6, a confidence interval slope of 1.025 to 1.037, and a confidence interval intercept of -2.7 to 1.1. In patient correlation studies at three separate POL sites, using the Alfa Wassermann ACE Axcel Clinical Chemistry System (y) and the Alfa Wassermann ACE Clinical Chemistry System (x), least-squares regression analysis yielded correlation coefficients of 0.9992 to 0.9996, standard error estimates of 5.9 to 8.4, confidence interval slopes of 0.989 to 1.024, and a confidence interval intercepts of -6.3 to 0.7. Detection limit: The detection limit was 11.6 mg/dL.
Conclusions:	Based on the foregoing data, the device is safe and effective. These data also indicate substantial equivalence to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

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4 Henderson Drive
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JUL 3 2012

Re: k113262
Trade/Device Name: ACE Cholesterol Reagent, ACE HDL-C Reagent, ACE LDL-C Reagent, ACE Triglycerides Reagent
Regulation Number: 21 CFR 862.1175
Regulation Name: Cholesterol (total) test system
Regulatory Class: Class I, meet limitations of exemption per 21 CFR 862.9(c)(4)
Product Code: CHH, LBS, MRR, CDT
Dated: May 31, 2012
Received: June 1, 2012

Dear Dr. Katz:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance...

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm

Sincerely yours,

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): _____

Device Name: ACE Cholesterol Reagent

Indications for Use: The ACE Cholesterol Reagent is intended for the quantitative determination of cholesterol concentration in serum using the ACE Axcel Clinical Chemistry System. Cholesterol measurements are used in the diagnosis and treatment of disorders involving excess cholesterol in the blood and lipid and lipoprotein metabolism disorders. This test is intended for use in clinical laboratories or physician office laboratories. For in vitro diagnostic use only.

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Prescription Use X (21 CFR Part 801 Subpart D) AND/OR Over-The-Counter Use. (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K113262

Indications for Use

510(k) Number (if known): _____

Device Name: ACE LDL-C Reagent

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Device Name: ACE Triglycerides Reagent

Indications for Use: The ACE Triglycerides Reagent is intended for the quantitative determination of triglyceride concentration in serum using the ACE Axcel Clinical Chemistry System. Triglyceride measurements are used in the diagnosis and treatment of patients with diabetes mellitus, nephrosis, liver obstruction, other diseases involving lipid metabolism or various endocrine disorders. This test is intended for use in clinical laboratories or physician office laboratories. For in vitro diagnostic use only.

Prescription Use X (21 CFR Part 801 Subpart D) AND/OR Over-The-Counter Use. (21 CFR Part 801 Subpart C)

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

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